

17581 U.S. PTO  
09/02/03

PATENT

15757 U.S. PTO  
10/653680  
09/02/03

Attorney's Docket No.: U 014797-5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of Inventor:

KEN-SHWO DAI

**WARNING:** *The Declaration must name all of the actual inventor(s).*

For (title):

HUMAN SACH-RELATED GENE VARIANTS ASSOCIATED WITH CANCERS

1. Type of Application

This new application is for a(n) (check one applicable item below):

- ☒ Original (nonprovisional)  
☐ Design  
☐ Plant

**WARNING:** *Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

**WARNING:** *Do not use this transmittal for the filing of a provisional application.*

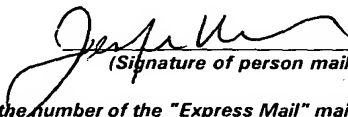
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CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **SEPTEMBER 2, 2003** in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV327549664US** addressed to the: Assistant Commissioner of Patents, Washington, D.C. 20231

**JENNIFER RASHKIN**

*(type or print name of person mailing paper)*



*(Signature of person mailing paper)*

**NOTE:** *Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).*

**WARNING:** *Certificate of mailing (first class) or facsimile transmission procedures of 37 CFR 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

(Application Transmittal [4-1]—page 1 of 7)

2. **Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)**

**NOTE:** If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

**WARNING:** If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

**WARNING:** When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional **must** be filed prior to the Saturday, Sunday or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).

- ☐ The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

**NOTE:** If one of the following 3 items apply, then complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED** and a **NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION**.

- ☐ Divisional.  
☐ Continuation.  
☐ Continuation-in-Part (C-I-P).

3. **Papers Enclosed That Are Required For Filing Date Under 37 CFR 1.53 (Regular) or 37 CFR 1.153 (Design) Application**

30

~~29~~ Pages of specification

4 Pages of claims

1 Pages of Abstract

38 Sheets of drawing

- ☒ formal  
☐ informal

**WARNING:** **DO NOT** submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

**NOTE:** "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c).

(complete the following, if applicable)

- ☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)". 37 C.F.R. 1.84(b).

**4. Additional papers enclosed**

- ☐ Preliminary Amendment
- ☐ Information Disclosure Statement (37 CFR 1.98)
- ☐ Form PTO-1449
- ☐ Citations
- ☐ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Other

**5. Declaration or oath**

- ☐ Enclosed  
executed by *(check all applicable boxes)*
  - ☐ inventor.
  - ☐ legal representative of inventor. 37 CFR 1.42 or 1.43
  - ☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.
    - ☐ This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. *See item 13 below for fee.*
- ☒ Not Enclosed.

**WARNING:** *Where the filing is a completion in the U.S. of an International Application but where a declaration is not available or where the completion of the U.S. application contains subject matter in addition to the International Application the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

- ☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all the above named inventor*. (The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

**NOTE:** *It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).*

- ☐ Showing that the filing is authorized. *(Not required unless called into question. 37 CFR 1.41(d).)*

**6. Inventorship Statement**

**WARNING:** *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

- ☐ The same
- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

**7. Language**

**NOTE:** *An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR*

1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37 CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

- ☒ English  
☐ non-English  
☐ the attached translation is a verified translation. 37 CFR 1.52(d).

**8. Assignment**

- ☐ An assignment of the invention to  
☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.  
☐ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters—one for the application and one for the assignment." Notice of May 4, 190 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 CFR 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993. 1150 O.G. 62-64.

**9. Certified Copy**

Certified copy of application

Country	Appln. No.	Filed
from which priority is claimed		
<input type="checkbox"/>	is attached.	
<input type="checkbox"/>	will follow.	

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

**10. Fee Calculation (37 CFR 1.16)**

- A. ☒ Regular Application

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Claims as Filed

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Number Filed	Number Extra	Rate	Basic Fee 37 CFR 1.16(a) \$750.00
Total Claims (37 CFR 1.16(c))	25 - 20 = 5 x \$	18.00	90.00
Independent Claims (37 CFR 1.16(b))	2 - 3 = 0 x \$	84.00	
Multiple dependent claim(s), if any (37 CFR 1.16(d))	+ \$	280.00	

- ☐ Amendment cancelling extra claims enclosed.
- ☐ Amendment deleting multiple-dependencies enclosed.
- ☐ Fee for extra claims is not being paid at this time.

**NOTE:** If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$

- B. ☐ Design application  
(\$330.00 — 37 CFR 1.16(f))

Filing Fee Calculation \$

- C. ☐ Plant application  
(\$520.00 — 37 CFR 1.16(g))

Filing Fee Calculation \$

**11. Small Entity Statement(s)**

- ☒ Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached or has been filed.

Filing Fee Calculation (50% of A, B or C above) \$

**NOTE:** Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

**12. Request for International-Type Search (37 CFR 1.104(d)) (Complete, if applicable)**

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

**13. Fee Payment Being Made At This Time**

- ☒ Not Enclosed
- ☒ No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

- ☐ Enclosed

☐ basic filing fee \$

- ☐ Recording assignment  
(\$40.00; 37 CFR 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")
- ☐ Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached.  
(\$130.00; 37 CFR 1.47 and 1.17(h)) \$
- ☐ For processing an application with a specification in a non-English language.  
(\$130.00; 37 CFR 1.52(d) and 1.17(k)) \$
- ☐ Processing and retention fee  
(\$130.00; 37 CFR 1.53(d) and 1.21(l))
- ☐ Fee for international-type search report  
(\$40.00; 37 CFR 1.21(e)). \$

*NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or the processing and retention fee of §1.21(l) must be paid within 1 year from notification under §53(d).*

Total fees enclosed \$

#### 14. Method of Payment of Fees

- ☐ Check in the amount of \$
  - ☐ Charge Account No. 12-0425 in the amount of \$
- A duplicate of this transmittal is attached.

*NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).*

#### 15. Authorization to Charge Additional Fees

**WARNING:** If no fees are to be paid on filing, the following items should not be completed.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 12-0425.
  - ☐ 37 CFR 1.16(a), (f) or (g) (filing fees)
  - ☐ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

*NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☐ 37 CFR 1.17 (application processing fees)

**WARNING:** While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under §1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27)

- ☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

*NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).*

*NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application ... prior to paying, or at the time of paying, ... issue fee". From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.*

**16. Instructions As To Overpayment**

- ☐ credit Account No. 12-0425  
☐ refund

  
\_\_\_\_\_  
Signature of Attorney

Reg. No. 25,858

Tel. No. (212) 708-1945

William R. Evans  
Ladas & Parry  
26 West 61 Street  
New York, NY 10023

☐ **Incorporation by reference of added pages**

*(Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)*

- ☐ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added \_\_\_\_

- ☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added \_\_\_\_

- ☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added \_\_\_\_

☒ **Statement Where No Further Pages Added**

*(If no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item:)*

- ☒ This transmittal ends with this page.

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: KEN-SHWO DAI

Serial No.:

Group No.:

Filed: SEPTEMBER 2, 2003

Examiner:

For: HUMAN SACH-RELATED GENE VARIANTS ASSOCIATED WITH  
CANCERS

Attorney Docket No.: U014797-5

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**WRITTEN ASSERTION OF SMALL ENTITY STATUS**

This is written assertion on the basis of:

- ☐ personal knowledge;  
☐ applicant's letter of \_\_\_\_\_;  
☒ applicant's agent's letter of September 2, 2003; or  
☐ other \_\_\_\_\_

by a practitioner (not necessarily of record) that the above application is entitled to small entity status and, therefore, fees.

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

- ☐ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

- ☒ as "Express Mail Post Office to Address"  
Mailing Label No. EV327549664US  
(mandatory)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: September 2, 2003

  
Signature

JENNIFER RASHKIN

*(type or print name of person certifying)*

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.



NOTE: "To establish small entity status after the payment of the basic filing or national stage fee as a non-small entity, a written assertion of small entity status is required to be submitted." Notice of September 8, 2000, 65 Fed. Reg. 54604, at 54609.

NOTE: 37 C.F.R. § 1.27(c)(1): "Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:

- (i) Be clearly identifiable;
- (ii) Be signed (see paragraph (c)(2) of this section); and
- (iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement."

NOTE: 37 C.F.R. § 1.27(c)(2): "Parties who can sign and file the written assertion. The written assertion can be signed by:

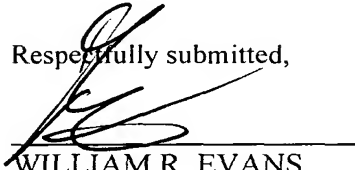
- (i) One of the parties identified in § 1.33(b) (e.g. an attorney or agent registered with the Office). § 3.73(b) of this chapter notwithstanding, who can also file the written assertion;
- (ii) At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), notwithstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or
- (iii) An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part."

35 C.F.R. § 1.33(b):

(b) Amendment and other papers. Amendments and other papers, except for written assertions pursuant to § 1.27(c)(2)(ii) of this part, filed in the application must be signed by:

- (1) A registered attorney or agent of record appointed in compliance with § 1.34(b);
- (2) A registered attorney or agent not of record who acts in a representative capacity under the provisions of § 1.34(a);
- (3) An assignee as provided for under § 3.71(b) of this chapter; or
- (4) All of the applicants (§ 1.41(b)) for patent, unless there is an assignee of the entire interest and such assignee has taken action in the application in accordance with § 3.71 of this chapter.

Respectfully submitted,

  
WILLIAM R. EVANS  
C/O LADAS & PARRY  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, N. Y. 10023  
REG. NO.: 25,858 (212) 708-1930